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SCHEINER, EXAMINER

18N1/0111

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| ART UNIT | PAPER NUMBER |
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| 1813 | 26 |

DATE MAILED: 01/11/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☑ This application has been examined ☑ Responsive to communication filed on 10/27/94 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

**Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:**

1. ☑ Notice of References Cited by Examiner, PTO-892.
2. ☑ Notice re Patent Drawing, PTO-948.
3. ☑ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☑ PTOL-413 Examiner Interview Summary Record

**Part II SUMMARY OF ACTION**

1. ☑ Claims 17-33 are pending in the application.
   Of the above, claims 17-25 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☑ Claims 26-33 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☑ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 17-25, drawn to a pharmaceutical composition containing polypeptide, antibodies and method, classified in Class 536, subclass 324.

II. Claims 26-33, drawn to DNA, classified in Class 536, subclass 23.1.

The inventions are distinct, each from the other because of the following reasons:

The compounds of Invention I and II are related in that the polypeptides of Group I may be obtained by expressing the DNA of Group II; while the antibody of Group I may obtained by employing the protein, of the same Group, as immunogen. However, the compounds of Inventions I and II are each distinct from the other because they are chemically different, having different structures, functions and properties. Additionally, the DNA of Group II may have materially different uses such as hybridization. Moreover, the protein of Group I may be obtained by directly isolating from brain rather than by recombinant expression.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification restriction for examination purposes as indicated is proper.

During a telephone conversation with Edward Gamson on December 1, 1994, a provisional election was made without traverse to prosecute the invention of Group II, claims 26-33.

Affirmation of this election must be made by applicant in responding to this Office action. Claims 23-25 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

Claims 26-33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 5,242,798. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented method of assaying for polypeptides can be performed based on the disclosed genetic information provided in the instant application. Thus, the method of determining amino acid residues are obvious over the DNA. Also in spite of the degeneracy of the genetic code, instant DNA can be obtained by employment of the peptides disclosed in the patented methods.

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. *In re Vogel*, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d).

The disclosure is objected to because of the following informalities: in claim 29, at line 4, the first occurrence of "having" should be deleted. Also, in claim 31, at lines 3 and 4,

the multiple "Figs." should not be abbreviated since only one period per claim is proper. Appropriate correction is required.

Claims 26-33 are vague and indefinite since the extent of subject matter to which the exclusionary right granted by patent is intended to apply cannot be determined. That is, the claims read on so many DNAs that one cannot determine which DNAs are intended. Moreover, it is not possible for the public to determine from the claims what they comprehend since they require explanations extraneous to both the specification and the claims. The claims have not been drafted with a reasonable degree of particularity since one cannot determine what is intended by "having about 500 to about 1800 nucleotide bases that is complementary to cytoplasmic messenger RNA of a mammal that is present in brain cells....". That is, these DNAs have not been defined by structure and the intended functions are unclear. That is, the disclosure in addition to DNA and mRNA, is directed to polypeptides requiring a structural genetic sequence of about 100 bases. Attention is directed to Ex parte Tanksley (26 USPQ2d 1384) wherein the Board noted that, under 35 USC 112, second paragraph, the claims must be so definite as to allow their comparison with the available art and must also make it possible for the public to determine from the claims what it is they comprehend. Only claims limited to the particular nucleic acid sequence as represented by instant Figures are so definite.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26-33 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to the DNA as represented by instant Figures. See M.P.E.P. §§ 706.03(n) and 706.03(z).

The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of nucleic acids broadly encompassed by the claims; and the number of DNAs encompassed by the claims is wholly indeterminate. Recently, in Ex parte Maizel (27 USPQ2d 1662), the Board considered that claims encompassing biologically functional equivalents were analogous to a single means claim and as such were more broad than the disclosure which disclosed only a single specific DNA segment known to the inventor. Such is the case here in which the specification is considered enabling only for claims limited to the specific nucleic acid sequence given in the Figures.

Claims 26-33 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Scheiner whose telephone number is (703) 308-1122.

Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM 1 Fax Center number is (703) 308-4227.

LAS

Laurie Scheiner/LAS

January 7, 1995

CHRISTINE M. NUCKER
SUPERVISORY PATENT EXAMINER
GROUP 180